DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2015

4WEB, Incorporated
% Richard Jansen, Pharm. D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Ft. Myers, Florida 33905

Re: K143258
Trade/Device Name: PLIF STS, TLIF STS and OLIF STS (Spine Truss System)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 6, 2015
Received: March 9, 2015

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143258

Device Name
PLIF STS, TLIF STS and OLIF STS (Spine Truss System)

Indications for Use *(Describe)*
The PLIF STS, TLIF STS and OLIF STS (Spine Truss System) are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K143258
510(k) Summary

Date Prepared: April 4, 2015

Contact: Jessee Hunt, President
4WEB, Inc.
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Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
richj@s-pineconsulting.com

Trade Name: PLIF STS, TLIF STS and OLIF STS (Spine Truss System)
Product Class: Class II
Classification: 21 CFR §888.3080
Common Name: Intervertebral Body Fusion Device
Product Codes: MAX
Panel Code: 87

Indications for Use:
The PLIF STS, TLIF STS and OLIF STS (Spine Truss System) are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Device Description:
The 4WEB PLIF STS, TLIF STS and OLIF STS (Spine Truss System) consists of a series of titanium implants that are designed to provide mechanical support to the spine while biologic fusion occurs. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.
The device is available in multiple sizes to accommodate varied patient's anatomy.

Predicate Device(s):
The 4WEB PLIF STS, TLIF STS and OLIF STS (Spine Truss System) is substantially equivalent to the Primary Predicate, the 4WEB ALIF STS (K112316). Additional predicates include the K2M Aleutian (K133614) and the Orthofix Forza (K103111).

Performance Standards:
Preclinical testing performed on the 4WEB PLIF STS, TLIF STS and OLIF STS (Spine Truss System) included static axial compression, static compression shear, dynamic axial compression, and dynamic compressive shear mechanical testing per ASTM F2077. The other mechanical test included subsidence per ASTM F2267-04 as well as expulsion testing to demonstrate substantial equivalence.

Technological Characteristics
The 4Web PLIF STS, TLIF STS and OLIF STS (Spine Truss System) is exactly the same as the primary predicate device in Indications for Use, materials, manufacturing and design. It is substantially equivalent to the additional predicate devices in sizes, surgical approaches risks.

Conclusion:
4WEB, Inc. concludes that the PLIF STS, TLIF STS and OLIF STS (Spine Truss System) devices are substantially equivalent to the predicate devices and raise no new questions of safety or effectiveness.